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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER	
ANDRES, JANET L	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,645	WOZNEY ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4, 6-8, 10-13, 18, 19, 27, 29, 31, and 36, drawn to polynucleotides of SEQ ID NO: 1 and means of expression, classified in class 435, subclasses 69.1, 320.1, and 325, and class 536, subclass 23.5.

II. Claims 1, 2, 4, 6-8, 10-13, 18, 19, 27, 29, 32, and 36, drawn to polynucleotides of SEQ ID NO: 3 and means of expression, classified in class 435, subclasses 69.1, 320.1, and 325, and class 536, subclass 23.5.

III. Claims 1, 3, 5, 6, 9, 18, 20-23, 27-29, 33, and 36, drawn to polynucleotides of SEQ ID NO: 5, classified in class 435, subclasses 69.1, 320.1, and 325, and class 536, subclass 23.5.

IV. Claims 1, 3, 5, 6, 9, 18, 20-23, 27-29, 34, and 36, drawn to polynucleotides of SEQ ID NO: 7, classified in class 435, subclasses 69.1, 320.1, and 325, and class 536, subclass 23.5.

V. Claims 1, 3, 5, 6, 9, 18, 20-23, 27-29, 35, and 36, drawn to polynucleotides of SEQ ID NO: 9, classified in class 435, subclasses 69.1, 320.1, and 325, and class 536, subclass 23.5.

VI. Claims 14, 16, and 30, drawn to polypeptides of SEQ ID NO: 2, classified in class 530, subclass 350.

VII. Claims 15, 17, and 30, drawn to polypeptides of SEQ ID NO: 4, classified in class 530, subclass 350.

VIII. Claim 24, drawn to polypeptides of SEQ ID NO: 6, classified in class 530, subclass 350.

IX. Claim 25, drawn to polypeptides of SEQ ID NO: 8, classified in class 530, subclass 350.

X. Claim 26, drawn to polypeptides of SEQ ID NO: 10, classified in class 530, subclass 350.

XI. Claims 37, 38, 41, and 42, drawn to antibody ligands for SEQ ID NO: 5, classified in class 530, subclass 387.9.

XII. Claims 37, 39, 41, and 43, drawn to peptide ligands for SEQ ID NO: 5, classified in class 530, subclass 300.

XIII. Claims 37, 40, 41, and 44, drawn to organic molecule ligands for SEQ ID NO: 5, classified in class 514, subclass 1.

XIV. Claims 37, 38, 41, and 42, drawn to antibody ligands for SEQ ID NO: 7, classified in class 530, subclass 387.9.

XV. Claims 37, 39, 41, and 43, drawn to peptide ligands for SEQ ID NO: 7, classified in class 530, subclass 300.

XVI. Claims 37, 40, 41, and 44, drawn to organic molecule ligands for SEQ ID NO: 7, classified in class 514, subclass 1.

XVII. Claims 37, 38, 41, and 42, drawn to antibody ligands for SEQ ID NO: 9, classified in class 530, subclass 387.9.

XVIII. Claims 37, 39, 41, and 43, drawn to peptide ligands for SEQ ID NO: 9, classified in class 530, subclass 300.

XIX. Claims 37, 40, 41, and 44, drawn to organic molecule ligands for SEQ ID NO:9, classified in class 514, subclass 1.

XX. Claims 37, 38, 46, 49, and 50, drawn to antibody ligands for SEQ ID NO: 2, classified in class 530, subclass 387.9.

XXI. Claims 37, 39, 45, 47, 49, and 50, drawn to peptide ligands for SEQ ID NO: 2, classified in class 530, subclass 300.

XXII. Claims 37, 40, 45, 48, 49, and 52, drawn to organic molecule ligands for SEQ ID NO: 2, classified in class 514, subclass 1.

XXIII. Claims 37, 38, and 46, drawn to antibody ligands for SEQ ID NO: 4, classified in class 530, subclass 387.9.

XXI. Claims 37, 39, 45, and 47, drawn to peptide ligands for SEQ ID NO: 4, classified in class 530, subclass 300.

XXII. Claims 37, 40, 45, and 48, drawn to organic molecule ligands for SEQ ID NO: 4, classified in class 514, subclass 1.

Claims appear in more than one group if they encompass more than one invention.

The inventions are distinct, each from the other because of the following reasons.

Inventions I-V are patentably distinct products. Although they are all polynucletotides, they are different molecules with different sequences; one sequence cannot be predicted from another. Furthermore, they require separate searches of the databases. Each individual sequence

represents a structurally and functionally distinct entity that must be searched separately, and the search and consideration of more than a single sequence constitutes an undue search burden.

Inventions VI-X are patentably distinct products. Although they are all polypeptides they are different molecules with different sequences; one sequence cannot be predicted from another. Furthermore, they require separate searches of the databases. Each individual sequence represents a structurally and functionally distinct entity that must be searched separately, and the search and consideration of more than a single sequence constitutes an undue search burden.

Inventions XI, XIV, XVII, XX, and XXIII are patentably distinct products. Although they are all antibodies, they are raised against different proteins and thus have different sequences. Further, they require separate searches of the protein databases, as well as of the non-patent literature, antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

Inventions XII, XV, XVIII, XXI, and XXIV are patentably distinct products. Although they are all peptides, they mimic proteins with different sequences and thus have different structural and functional features. Further, they require separate searches of the protein databases, since the proteins they mimic are not identical.

Inventions XIII, XVI, XIX, XXII, and XXV are patentably distinct products. Although they are all small organic molecules, they mimic proteins with different sequences and thus have different structural and functional features. They further require separate searches of the protein sequences, since the structures they mimic are different, and require separate searches of the non-patent literature as well, since they may be characterized in the literature prior to the discovery of a particular functional property.

The polypeptide of groups VI-X and polynucleotides of groups I-V are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In addition, while a polypeptide of groups VI-X can made by methods using the polynucleotides that fall within the scope of groups I-V, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I-V and VI-X are patentably distinct.

Furthermore, searching the inventions of groups I-V and VI-X together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of the groups together.

The polynucleotide of groups I-V and the antibodies of groups XI, XIV, XVII, XX, and XXIII are patentably distinct for the following reasons. The antibodies include, for example,

IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibodies which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of groups I-V will not encode an antibody of group XI, XIV, XVII, XX, and XXIII, and the antibodies of groups XI, XIV, XVII, XX, and XXIII cannot be encoded by a polynucleotide of group I. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of the groups would impose a serious search burden since a search of the polynucleotide of groups I-V is would not be used to determine the patentability of an antibody of group XI, XIV, XVII, XX, and XXIII, and vice-versa.

The polynucleotide of groups I-V and the peptides of groups XII, XV, XVIII, XXI, and XXIV are patentably distinct for the following reasons. Peptides are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and peptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of groups I-V will not encode a peptide of group XII, XV, XVIII, XXI, and XXIV, and the peptides of groups

XII, XV, XVIII, XXI, and XXIV cannot be encoded by a polynucleotide of groups I-V. Therefore the polynucleotide and peptide are patentably distinct.

The polynucleotide and peptide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of the groups would impose a serious search burden since a search of the polynucleotide of groups I-V is would not be used to determine the patentability of peptides of group XII, XV, XVIII, XXI, and XXIV and vice-versa.

The polynucleotide of groups I-V and the organic molecules of groups XIII, XVI, XIX, XXII, and XXV are patentably distinct for the following reasons. Organic molecules are composed of carbon backbones, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; there is no physical relationship between them. In the present claims, a polynucleotide of groups I-V will not encode an organic molecule of group XIII, XVI, XIX, XXII, and XXV, and the organic molecule of groups XIII, XVI, XIX, XXII, and XXV cannot be encoded by a polynucleotide of groups I-V. Therefore the polynucleotide and organic molecules are patentably distinct.

The polynucleotide and organic molecule inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of the groups would impose a serious search burden since a search of the polynucleotide of groups I-V would not be used to determine the patentability of an organic molecule of group XIII, XVI, XIX, XXII, and XXV and vice-versa.

The polypeptides of groups VI-X and the antibodies of groups XI, XIV, XVII, XX, and XXIII are patentably distinct for the following reasons:

While the inventions of both sets of groups are polypeptides, in this instance the polypeptide of groups VI-X is a single chain molecule that functions as an receptor, whereas the polypeptide of groupa XI, XIV, XVII, XX, and XXIII encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide and the antibody are structurally distinct molecules; any relationship between a polypeptide of groups VI-X and an antibody of groups XI, XIV, XVII, XX, and XXIII is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

Furthermore, searching the inventions of groups VI-X and groups XI, XIV, XVII, XX, and XXIII would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of groups XI, XIV, XVII, XX, and XXIII. Furthermore, antibodies which bind to an epitope of a polypeptide of group VI-X may be known even if a polypeptide of groups VI-X is novel. In addition, the technical literature search for the polypeptide of groups VI-X and the antibody of groups XI, XIV, XVII, XX, and XXIII are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polypeptides of groups VI-X and the peptides of groups XII, XV, XVIII, XXI, and XXIV are patentably distinct for the following reasons:

While the inventions of both sets of groups are peptides, in this instance the polypeptide of groups VI-X is a single chain molecule that functions as an receptor, whereas the peptides of groups XII, XV, XVIII, XXI, and XXIV encompasses small peptides that bind to these receptors. Thus the polypeptide and the peptide are structurally distinct molecules; there is no structural relationship between a polypeptide of groups VI-X and peptides of groups XII, XV, XVIII, XXI, and XXIV.

Furthermore, searching the inventions of groups VI-X and groups XII, XV, XVIII, XXI, and XXIV would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and a peptide which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the peptides of groups XII, XV, XVIII, XXI, and XXIV. Furthermore, peptides that bind to a polypeptide of group VI-X may be known even if a polypeptide of groups VI-X is novel. In addition, the technical literature search for the polypeptide of groups VI-X and the peptides of groups XII, XV, XVIII, XXI, and XXIV are not coextensive, e.g., peptides may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polypeptide of groups VI-X and the organic molecules of groups XIII, XVI, XIX, XXII, and XXV are patentably distinct for the following reasons. Organic molecules are

composed of carbon backbones, and polypeptides, which are composed of amino acids, are structurally distinct molecules; there is no physical relationship between them.

The polypeptide and organic molecule inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of the groups would impose a serious search burden since a search of the polypeptide of groups VI-X would not be used to determine the patentability of an organic molecule of group XIII, XVI, XIX, XXII, and XXV and vice-versa.

The peptides of groups XII, XV, XVIII, XXI, and XXIV and the antibodies of groups XI, XIV, XVII, XX, and XXIII are patentably distinct for the following reasons:

While the inventions of both sets of groups are polypeptides, in this instance the peptide of groups XII, XV, XVIII, XXI, and XXIV is a single chain molecule that binds to a receptor, whereas the polypeptide of groups XI, XIV, XVII, XX, and XXIII encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide and the antibody are structurally distinct molecules; there is no physical relationship between them.

Furthermore, searching the inventions of groups XII, XV, XVIII, XXI, and XXIV and groups XI, XIV, XVII, XX, and XXIII would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. An antibody and a peptide that bind to the same receptor require different searches, since the sequences are not related. In addition, the technical literature search for the peptides of groups XII, XV, XVIII, XXI, and XXIV and the antibodies of groups XI, XIV, XVII, XX, and XXIII are not

coextensive, e.g., peptides and antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The antibodies of groups XI, XIV, XVII, XX, and XXIII and the organic molecules of groups XIII, XVI, XIX, XXII, and XXV are patentably distinct for the following reasons. Organic molecules are composed of carbon backbones, while groups XI, XIV, XVII, XX, and XXIII encompass antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the organic molecules and the antibody are structurally distinct molecules; there is no physical relationship between them.

The antibody and organic molecule inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of the groups would impose a serious search burden since a search of the antibodies of groups XI, XIV, XVII, XX, and XXIII would not be used to determine the patentability of an organic molecule of group XIII, XVI, XIX, XXII, and XXV and vice-versa.

The peptides of groups XII, XV, XVIII, XXI, and XXIV and the organic molecules of groups XIII, XVI, XIX, XXII, and XXV are patentably distinct for the following reasons. Organic molecules are composed of carbon backbones, while groups XII, XV, XVIII, XXI, and XXIV encompass molecules that are composed of amino acids that can be structurally unrelated to other organic molecules. Thus the organic molecules and the peptides are structurally distinct molecules; there is no physical relationship between them.

The peptides and organic molecule inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of the groups would impose a serious search burden since a search of the peptides of groups XII, XV, XVIII, XXI, and XXIV would not be used to determine the patentability of an organic molecule of group XIII, XVI, XIX, XXII, and XXV and vice-versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the searches required for the groups are different, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
4 October 2004

JANET ANDRES
PRIMARY EXAMINER